at, for example, Example 7. The amendment to claim 48 is supported by the specification at, for example, Example 3. Solely in an effort to advance prosecution of the instant application and not in acquiescence of any rejection, claims 36-43 and 45-47 have been cancelled. Applicants note that claims 36-43 and 45-47 were pursued in an effort to provoke an interference with U.S. Patent 6,127,175. An interference with the '175 patent has been declared with respect to the parent of the instant application. Accordingly, claims 36-43 and 45-47 are cancelled herein with the expectation that the interfering subject matter disclosed in those claims will be addressed in that interference proceeding. Separate documents setting forth the precise changes to the claims, as well as the text of the pending claims, are attached.

The Pending Claims

Claims 44 and 48 are pending. Claim 44 is directed to a plasmid comprising a reading frame ORF6 of an E4 region of an adenovirus genome, while claim 48 is directed to a defective recombinant adenovirus that requires, for replication, complementation *in trans* of one or more essential gene functions of an E1 region and an E4 region of an adenovirus genome, wherein all or part of the E1 region and the whole of the E4 region is deleted.

The Office Action

The Office Action sets forth the following rejections:

(a) claims 36-43 and 45-47 have been rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement and/or written description,

(b) claims 36-43 and 45-47 have been rejected under 35 U.S.C. § 102(a) and (e) as allegedly being anticipated by U.S. Patent 6,127,175 (Vigne et al.),

(c) claims 36-48 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patents 5,851,806 or 5,994,106 (Kovesdi et al.),

(d) claim 44 has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Weinberg et al. (*PNAS*, *80*, 5383-5386 (1983)), as evidenced by Leza et al. (*J. Virol.*, *63*(7), 3057-3064 (1989)),

(e) claims 36-43 and 45-48 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 9-17, 32-46, and 53-58 of U.S. Patent 5,851,806, and claims 1, 4, 7, 9-11, 14, 17, 19, 22, and 24 of U.S. Patent 5,994,106,

(f) claims 36-48 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 19-26, 36-40, 43-56, 62-71, and 76-95 of U.S. Patent Application No. 08/258,416, claims 36-38, 52, 53,

68-70, 74, and 75 of U.S. Patent Application No. 09/261,922, claims 36 and 40-42 of U.S. Patent Application No. 09/766,405, and/or claims 36-39 of U.S. Patent Application No. 09/797,064.

The Office Action further asserts that claims 36-48 are not entitled to the benefit of priority of the filing date of the parent of the instant application.

Claims 36-43 and 45-47 have been cancelled, thereby rendering moot the rejections under Section 112, first paragraph, Section 102 (a) and (e), and obviousness-type double patenting over U.S. Patents 5,851,806 or 5,994,106. Reconsideration of the remaining rejections is hereby requested.

Discussion of Priority

The Office contends that the claimed invention is not described or fully enabled either by the instant specification or the specification of the parent application for the reasons set forth in the rejection under Section 112, first paragraph. Applicants note that only cancelled claims 36-43 and 45-47 were rejected under Section 112, first paragraph. Pending claims 44 and 48 were not cited in the rejection.

In addition, the subject matter of claims 44 and 48 is fully enabled by and sufficiently described in the instant specification and the specification of the parent '416 application. For example, a plasmid comprising ORF6 of an adenoviral E4 region (see, e.g., claim 44), as well as a method of making and using the plasmid to construct a complementing cell line, is described in Example 9. A recombinant adenovirus that requires, for replication, complementation *in trans* of one or more essential gene functions of an E1 region and an E4 region of an adenovirus genome, wherein all or part of the E1 region and the whole of the E4 region is deleted (see, e.g., claim 48) is described throughout the specification and, in particular, in Example 3, which describes $Ad_{GV}.12$, an E1-deficient adenoviral vector comprising a complete elimination of the E4 region.

Accordingly, the pending claims, i.e., claims 44 and 48, are entitled to a priority date of June 10, 1994, corresponding to the filing date of the parent of the instant application.

Discussion of Rejection under 35 U.S.C. § 102(b)

Claims 36-48 have been rejected under Section 102(b) as allegedly being anticipated by U.S. Patents 5,851,806 or 5,994,106 (Kovesdi et al.). Claims 36-43 and 45-47 have been cancelled. In addition, claim 44 has been rejected as allegedly being anticipated by the Weinberg et al. reference, as evidenced by the Leza et al. reference. The rejection of claims 44 and 48 is traversed for the reasons set forth below.

The basis of the rejection over U.S. Patents 5,851,806 and 5,994,106 appears to be that the pending claims allegedly are not supported by the instant application or the parent application and, therefore, the pending claims are not entitled to a priority date of June 10, 1994, the filing date of the earliest filed parent of the instant application. However, as set forth above, the disclosure of the specification supports each and every element of the pending claims and provides sufficient guidance as to enable the ordinarily skilled artisan to make and use the present invention as claimed. Accordingly, Applicants submit that the presently claimed invention is clearly and fully supported and enabled by the disclosure of the parent applications and, therefore, is entitled to a priority date of June 10, 1994, which is prior to the publication date of U.S. Patents 5,851,806 or 5,994,106. As such, the U.S. Patents 5,851,806 or 5,994,106 are not prior art to the instant application, and the rejection under Section 102(b) should be withdrawn.

Claim 44 has been rejected as allegedly being anticipated by the Weinberg et al. reference, as evidenced by the Leza et al. reference. The Weinberg et al. reference discloses plasmids comprising the complete E4 region of adenovirus (see, for example, Figure 1). Claim 44 is directed to a plasmid comprising a reading frame ORF6 of an adenoviral E4 region. ORF6 is under the control of a heterologous inducible promoter. There is no teaching or suggestion in the Weinberg et al. reference to drive expression of the E4 region, or a portion thereof, much less ORF6, with a heterologous promoter. The Leza et al. reference does not cure the deficiencies of the Weinberg et al. reference by merely disclosing that the E4 promoter is an inducible promoter. In that the Weinberg et al. and Leza et al. references do not teach or suggest every feature of claim 44, the claim must be considered as defining novel subject matter over the cited references, and the Section 102(b) rejection should be withdrawn.

Discussion of Provisional Obviousness-Type Double Patenting Rejection

Claims 36-48 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 19-69, 36-40, 43-56, 62-71, and 76-95 of U.S. Patent Application No. 08/258,416, claims 36-38, 52, 53, 68-70, 74, and 75 of U.S. Patent Application No. 09/261,922, claims 36 and 40-42 of U.S. Patent Application No. 09/766,405, and/or claims 36-39 of U.S. Patent Application No. 09/797,064.

Claims 36-43 and 45-47 have been cancelled. Accordingly, the only remaining rejection is that of claims 44 and 48 as allegedly being unpatentable over claims 19-69, 36-40, 43-56, 62-71, and 76-95 of U.S. Patent Application No. 08/258,416. According to M.P.E.P. § 804, a provisional obviousness-type double patenting rejection is proper unless the provisional rejection is the only rejection remaining in one of the applications. As stated

in M.P.E.P. § 804: "If the 'provisional' double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the 'provisional' double patenting rejection in the other application into a double patenting rejection at the time the one application issues as a patent."

In that the provisional obviousness-type double patenting rejection is the only remaining rejection in the instant application, Applicants assert that the rejection should be withdrawn in the instant application, and the instant application be allowed to issue.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,

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Date: May 28, 2002

In re Appln. of Kovesdi et al.
Application No. 09/964,065

CERTIFICATE OF MAILING

I hereby certify that this RESPONSE TO OFFICE ACTION (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

Date: May 28, 2002 Frances Sanchez

PATENT
Attorney Docket No. 213257

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kovesdi et al.

Application No. 09/964,065

Filed: September 26, 2001

For: COMPLEMENTARY ADENOVIRAL VECTOR SYSTEMS AND CELL LINES

Art Unit: 1632

Examiner: Priebe, S.

AMENDMENTS TO CLAIMS
MADE IN RESPONSE TO OFFICE ACTION DATED FEBRUARY 27, 2002
(deletions indicated by brackets, additions indicated by underlining)

Amendments to existing claims:

[36. A recombinant cell line for the production of a defective adenovirus, comprising, inserted into its genome, part of an adenovirus E4 region comprising an ORF6 reading frame under the control of a functional promoter, wherein the inserted E4 region does not contain a functional ORF4 reading frame.]

[37. The cell line according to claim 36, wherein the E4 region is derived from a group C human adenovirus genome.]

[38. The cell line according to claim 37, wherein the E4 region is derived from the genome of an Ad2 or Ad5 adenovirus.]

[39. The cell line according to claim 36, wherein the promoter is an inducible promoter.]

[40. The cell line according to claim 36, which transcomplements for the E1 region.]

[41. The cell line according to claim 40, which is derived from cell line 293.]

[42. The cell line according to claim 36, wherein the part of the E4 region does not contain ORF4.]

[43. The cell line according to claim 42, wherein the part of the E4 region does not contain ORF1-ORF4.]

44. (Amended) A plasmid comprising [part of an E4 region of an adenovirus genome carrying] a reading frame ORF6 of an E4 region of an adenovirus genome under the control of [an] a heterologous inducible promoter.

[45. A method for the production of a recombinant adenovirus which is defective at least for the E4 region, comprising infecting the cell line of claim 36 with the E4 defective adenovirus and harvesting the adenovirus.]

[46. The method according to claim 45, wherein the cell line cells are transformed with one or more plasmids providing the various regions of the genome of the defective recombinant adenovirus.]

[47. The method according to claim 46, wherein the recombinant adenovirus is defective for E1 and E4 regions.]

48. (Amended) A defective recombinant adenovirus [ΔE1, ΔE4,] that requires, for replication, complementation *in trans* of one or more essential gene functions of an E1 region and an E4 region of an adenovirus genome, wherein all or part of the E1 region and the whole of the E4 region is deleted.